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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/655,911

09/05/2003

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/655,911	Applicant(s) ANGEL ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1, 3, 4, 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of response dated 4-10-09 is acknowledged.

The following rejection of record maintained:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 3, 4 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,962,532 to Campbell and Ann Jones et al (Clinical toxicology, abstract only) in view of Wholehealthmd and US 5910512 to Conant.
2. **A full article of Ann Jones (Clinical Toxicology) has been attached to this action.**

Campbell teaches methods and compositions for treating pain at a specific site with an effective amount of capsaicin. Campbell teaches that while capsaicin is effective in pain treatment, the side effects of capsaicin include activation of nociceptors in peripheral tissues desensitization of peripheral nociceptors, cellular degeneration of sensitive A-fiber and C-fiber etc (col. 1, col. 3-4). In order to overcome the above effects, Campbell teaches that anesthesia is first provided to the site of where capsaicin needs to be administered, followed by administration of capsaicin (summary of invention). Additionally, Campbell states that any irritant effect of capsaicin is relieved by administering a narcotic analgesic (see claim 9 of Campbell). Campbell fails to teach the claimed kit and also fails to teach the second component of instant claims.

Wholehealthmd teaches a capsaicin product for relieving pain and arthritis. The reference suggests that capsaicin causes stinging and burning sensation, and suggests washing the hands thoroughly after applying the cream, with soapy water (page 3, special concerns). Wholehealthmd does not mention the solubility of capsaicin.

Ann Jones (abstract) studied the effect of cool tap water and oils in the removal of burning caused by capsaicin on the skins of elderly women. Ann Jones states that in a survey of elderly Hispanic women, treatment with oils or cool tap water were frequently used home remedies for burning caused by hot chili peppers. Twenty female subjects immersed their hands in standardized slurry of green chili for 40 minutes; afterwards one hand was placed in cool tap water and the other in vegetable oil for a total of 75 minutes. Pain was scored using a visual analog scale while the hands were immersed in the chili slurry, test baths, and after drying. The difference in pain score was calculated for each subject. Analysis was by pooled regression cool tap water immersion initially provided more relief while vegetable oil provided better long-term relief from the pain of "chili burns".

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to include a component such as vegetable oil of Ann Jones or any suitable solubilizer which solubilizes and removes the residual capsaicin after applying, in the teachings of Campbell, because Wholehealthmd suggests removing capsaicin to avoid burning and stinging and Conant teaches that capsaicin is insoluble in water but is soluble in alcohol, oils, grease, chloroform etc. A skilled artisan would have employed a suitable solvent such as oils of Anne Jones to remove capsaicin of Campbell because

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Anne Jones teaches that vegetable oils are very effective in providing long term relief from the burning pain caused by chili peppers, which by applicants' own admission (page 1, [0003]) contains capsaicin and causes burning. A skilled artisan would have expected to reduce burning caused by capsaicin of Campbell, by 1) desensitizing with an anesthetic as well as 2) removing the burning pain caused by capsaicin from the skin with vegetable oils. In this regard, Conant teaches that capsaicin is solubilized in oils, grease, chloroform etc (col. 1, L 35-41). With respect to the claimed solubility, Anne Jones teaches oils for reducing burning for a long time and therefore the burden is on applicants to show that oils do not possess the claimed solubility for capsaicin.

While the cited references fail to teach a kit and a separately packaged second composition with the claimed solubility of capsaicin in the second composition, it would have been obvious for a skilled artisan to first apply capsaicin for its intended pharmacological effect and then apply a soap or an oily solution to remove the irritant effect so as to allow the effect of capsaicin be achieved. Further, the solution intended to remove the irritant effect of capsaicin should have to be solubilizing capsaicin so as to successfully remove the irritant effect.

3. Claims 1, 3, 4 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over unpatentable US 2002/0002406 Robbins et al (PTO-1449 of 3-14-08) and Ann Jones et al in view of Wholehealthmd and US 5910512 to Conant.

Robbins teaches application of capsaicin or its analogs for treating pain, including neuropathic pain. Robbins teaches capsaicin or its analogue is applied to the skin in the form of a transdermal patch containing greater than 5% to 10% capsaicin (0008-0010; 0012). The steps of application in example 1 describes applying an anesthetic (ELMA- see 0012 for description), followed by capsaicin and removal of the capsaicin. Instant description at 0045 describes the same capsaicin anesthetics as that of Robbins. Robbins teaches that while capsaicin is effective in treating neuropathic pain, it also causes side effects such as burning and therefore suggests applying a desensitizer of C fibers, such as an anesthetic so the burning would be reduced.

Robbins fails to teach the claimed kit and a second component to solubilize capsaicin and the instructions of use.

The teachings of Anne Jones, Wholehealthmd and Conant are described in the preceding paragraphs.

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to include a component such as vegetable oil of Ann Jones or any suitable solubilizer which solubilizes and removes the residual capsaicin after applying, in the teachings of Robbins, because Wholehealthmd suggests removing capsaicin to avoid burning and stinging and Conant teaches that capsaicin is insoluble in water but is soluble in alcohol, oils, grease, chloroform etc. A skilled artisan would have employed a suitable solvent such as oils of Anne Jones to remove capsaicin of Robbins because Anne Jones teaches that vegetable oils are very effective in providing long term relief from the burning pain caused by chili peppers, which by applicants' own admission

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(page 1, [0003]) contains capsaicin and causes burning. A skilled artisan would have expected to reduce burning caused by capsaicin of Robbins, by 1) desensitizing with an anesthetic as well as 2) removing the burning pain caused by capsaicin from the skin with vegetable oils. In this regard, Conant teaches that capsaicin is solubilized in oils, grease, chloroform etc (col. 1, L 35-41). With respect to the claimed solubility, Anne Jones teaches oils for reducing burning for a long time and therefore the burden is on applicants to show that oils do not possess the claimed solubility for capsaicin.

While the cited references fail to teach a kit and a separately packaged second composition with the claimed solubility of capsaicin in the second composition, it would have been obvious for a skilled artisan to first apply capsaicin for its intended pharmacological effect and then apply a soap or an oily solution to remove the irritant effect so as to allow the effect of capsaicin be achieved. Further, the solution intended to remove the irritant effect of capsaicin should have to be solubilizing capsaicin so as to successfully remove the irritant effect.

Response to Arguments

4. Applicant's arguments filed 4-10-09 have been fully considered but they are not persuasive.

5. Claims 1, 3, 4 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,962,532 to Campbell and Ann Jones et al (Clinical toxicology, abstract only) in view of Wholehealthmd and US 5910512 to Conant.

Applicants disagree that a case of obviousness has been established on the basis that there is no logical connection between Campbell and Wholehealthmd. It is argued that Campbell teaches prior administration of anesthesia to the site of capsaicin administration to reduce capsaicin's side effects. Campbell also describes the administration of narcotics to treat break through pain that occurs despite the use of an anesthetic (see, e.g., column 2, lines 38-43; and column 4, lines 46-51 of Campbell). These solutions to the problem of capsaicin side-effects are also recognized by the Office on page 4 of the instant Office Action. It is argued that Wholehealthmd clearly describes a different method of handling the burning side-effects of capsaicin i.e., using soapy water to wash off the capsaicin on the skin. Applicants argue one of skill would not reasonably expect that simple washing, as described by Wholehealthmd, would resolve the burning side-effects when harsher methods, i.e., use of anesthetics and narcotics, are being used by Campbell. Applicants refer to the previously provided evidence that soapy water fails to solubilize capsaicin in the claimed amounts (see Appendix A of the Supplemental Amendment filed on November 9, 2005), and thus would not effectively remove capsaicin from the skin. Applicants argue that one of skill would not look to wash capsaicin from the skin, as taught by Wholehealthmd, because Campbell focuses on counteracting the burning and stinging by administering additional drugs, i.e., anesthetics and narcotic agents. Applicants argue that Ann Jones and Conant appear to have been added for their disclosure of oils and other solvents of capsaicin, and thus, need not be discussed in detail here. Lastly, the motivation to employ the method of Ann Jones over the argued harsher methods of Campbell comes

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from the teaching that capsaicin is freely soluble in oils and hence a skilled artisan would expect a complete removal of capsaicin, which also claimed in the instant application. Applicants have not provided any evidence to show that the oils of Anne Jones are not effective in Solubilizing or removing capsaicin.

6. Applicants' arguments are not persuasive for the following reasons: first, instant claims are directed to a kit "comprising" components a) and b), which transitional phrase does not exclude components such as anesthetic and narcotic of Campbell. While it is true that Wholehealthmd teaches soapy water for cleansing, the rejection is not based on this reference alone. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The teachings of Anne Jones have been cited to show that capsaicin is soluble in oils (admitted by applicants). A full article of Ann Jones is attached to this action where it is disclosed that capsaicin is freely soluble in fatty oils and volatile oils (first full paragraph of page 484). Instant claims do not recite any particular component that solubilizes capsaicin and instead only requires a component in which capsaicin is soluble at least about 10% and the second component cleanses bodily surfaces by removing capsaicin. Figure 1 on page 487 of Ann Jones shows that oil is superior in relieving the burn due to capsaicin. In conclusion (page 489), Ann

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Jones states that hands should be washed with soap water and then immersed in oils to get the complete effect. Thus, Ann Jones certainly teaches benefits over just soap water treatment (also taught by Wholehealthmd). Third, the combination of references is appropriate because the teachings of the prior art are analogous and each one of them is directed to relieving the irritation or burning caused by capsaicin treatment. Ann Jones not only states that the burning is due to handling of peppers but also due to the topical analgesic preparations containing capsaicin (page 488, second full paragraph). Even in the absence of a full disclosure of Ann Jones, the teachings of Conant also recognize that capsaicin is soluble in oils and therefore applicants' arguments are not persuasive.

7. Claims 1, 3, 4 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over unpatentable US 2002/0002406 Robbins et al (PTO-1449 of 3-14-08) and Ann Jones et al in view of Wholehealthmd and US 5910512 to Conant.

8. Applicants again argue that Robbins describes the administration of anesthesia and narcotics to treat break through pain that occurs at the site of administering capsaicin. Applicants presented the same arguments as above with respect to the teachings of Ann Jones et al, Wholehealthmd and US 5910512 to Conant.

9. However, as explained above the instant transitional phrase does not exclude components such as anesthetic and narcotic of Robbins. Further, the rationale to combine the teachings of Ann Jones et al, Wholehealthmd and US 5910512 to Conant with Robbins is the same as that in the combination of Ann Jones et al, Wholehealthmd and US 5910512 to Conant with Campbell. Accordingly, the examiner's above response

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to applicants' arguments regarding the teachings of Ann Jones et al, Wholehealthmd and US 5,910,512 to Conant is reiterated here. For the reasons mentioned above, the rejections have been maintained.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner,
Art Unit 1611
June 11, 2009